

REMARKS

Claims 57-61 are active in this application.

The presently claimed invention is drawn to a method for suppressing bacterial growth in a blood fraction, comprising adding to a blood fraction a compound selected from the group consisting of L-carnitine, salts of L-carnitine, alkanoyl carnitines, salts of alkanoyl carnitines, and mixtures thereof, in an amount effective to suppress bacterial growth in said blood fraction,

wherein said blood fraction is a *prestorage-leuko-reduced* platelet concentrate, and wherein said method comprises suspending said *prestorage-leuko-reduced* platelet concentrate in a support solution which comprises said compound. (see Claim 57) Applicants submit that the combined disclosures of Sweeney et al, US 5,747,536, Tegos et al, and Ogawa et al can not affect the patentability of the claimed invention and reconsideration of the outstanding rejections is requested in view of the amendments and remarks herein.

The rejection of Claims 57-61 under 35 U.S.C. §103(a) over Sweeney et al in combination with US 5,747,536, Tegos et al, and Ogawa et al is respectfully traversed.

With respect to Claims 57-61, Applicants submit that Sweeney et al do not disclose or suggest the treatment of a prestorage-leuko-reduced platelet concentrate. On the contrary, Sweeney et al use standard non-leuko-reduced platelet concentrate (see page 31, line 13). Thus, the material used in the presently claimed invention differs from that disclosed in Sweeney et al.

It is further noted that there is no disclosure or suggestion in either Sweeney et al or

US 5,747,536 that the method disclosed by Sweeney et al would work with leuko-reduced platelet concentrate. Thus, the combination of Sweeney et al and US 5,747,536 would fail to provide sufficient motivation for the artisan to perform the method as claimed, much less have an expectation of success.

Further, US 5,747,536 discloses the equivalence of the various acyl carnitines, but in a completely different context. The use of said compounds in the treatment of cardiovascular, disorders, peripheral vascular diseases and peripheral diabetic neuropathy cannot be taken into consideration by the person of ordinary skill in the art of *platelet storage*. This skilled artisan would be totally unaware of method of treatment of cardiovascular, disorders, peripheral vascular diseases and peripheral diabetic neuropathy and would not address his attention there to try to find a possible suggestion with respect to platelet storage. Thus, US 5,747,536 fails to offer anything further to the disclosure of Sweeney et al.

Recognizing the foregoing, the Examiner now cites Tegos et al and Ogawa et al. However, Applicants note that none of Sweeney et al, US 5,747,536, Tegos et al, and Ogawa et al make any correlation between glycolysis and suppression of bacterial growth. To the contrary, the art uses different means to achieve sterilization. See specification, in particular the section IRRADIATION.

Tegos et al do not add anything useful to the art, since they teach glycolytic enzymes are stable for 72 hours, which was the storage period at the time of the publication of Tegos et al (1979). Nothing is known for longer periods, except that some enzymes start to degrade before, and the reference does not exclude that later other enzyme can start to degrade. Later, the concern of extended storage periods for platelet concentrates arose. Sweeney et al reached 5 days in 1998. Even if Ogawa et al disclose leukodepleting platelet products as

alleged by the Examiner, this reference does not relate to the problem of storage, and gives no significant contribution thereto. As stated above, US 5,747,536 establishes equivalence among different carnitine derivatives, but for a completely different purpose. The skilled person cannot take for granted that this equivalence is true also in the field of platelet concentrate storage.

The present invention achieves an improved result in that storage time is extended to 8 days (specification, page 31). In this art, progress is made by little steps, but every extension of storage life is of utmost importance in saving lives of human beings. For example, in disaster situations (e.g., a hurricane, an earthquake, a terrorist attack) availability of blood supply is critical and every single day of extended storage is critical. Despite this critical need, no one in the art reached 8 day storage before the present invention.

Thus, for the reasons given above and based ion the advantages clearly shown in the present specification, Applicants submit that the present invention is not obvious over the combined disclosures of Sweeney et al, US 5,747,536, Tegos et al, and Ogawa et al. Specifically, Applicants submit that absent the present application the skilled artisan would not have known or assumed that by adding acetyl L-carnitine to platelet concentrates, even if by the same method as Sweeney et al to reduce glycolysis, would have attained the result to suppress bacterial growth and prolong storage time of the concentrates.

In view of the foregoing, withdrawal of these grounds of rejection is requested.

Applicants submit that the present application is now in condition for allowance.

Early notification of such action is earnestly solicited.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.
Norman F. Oblon



Vincent K. Shier, Ph.D.
Registration No. 50,552

Customer Number

22850

Tel: (703) 413-3000
Fax: (703) 413-2220
(OSMMN 08/03)